REMARKS

Claims 1-5 are currently pending in the present application.

The drawings stand objected to as failing to illustrate a number of features of the present invention.

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as unpatentable over, either U.S. Patent No. 6,235,060 to Kubein-Meesenburg, *et al.* ("Kubein-Meesenburg") or U.S. Patent No. 5,871,539 to Pappas ("Pappas").

The Applicants have carefully reviewed the August 16, 2004 Office Action, and respectfully submit the foregoing amendments and following remarks.

1. The Drawing Objections Have Been Addressed.

The Applicants respectfully submit the attached replacement drawing sheet for Examiner approval of proposed changes to the figure. The proposed changes are marked in red ink. Specifically, the Applicants are proposing changes to:

- more clearly associate the angle δ with reference lines, both at the effective resultant force lines at the bottom of the figure, and at the ti lines at the upper right of the figure;
- more clearly label the two examples of the momentary axis of rotation P, which were illustrated in the figure with numbers 1, 2 adjacent to a "P," as "P1" and "P2";
- more clearly label the two pairs of examples of the contact points C, which were illustrated in the figure with numbers 1, 2 adjacent to a "C" next to each contact point, as "C1" and "C2";
- more clearly label the two resultant force lines F, which were illustrated in the figure with numbers 1, 2 adjacent to an "F" next to each force line, as "F1" and "F2"; and

- add reference labels β_1–β_4 to highlight the location of the angles described in the original specification at page 4 as preferably not exceeding 40 degrees.

Consistent with the last of the above proposed drawing changes, and the original disclosure at page 4, lines 1-3, the Applicants have amended the specification at page 5 to add a sentence to the end of paragraph [0018] to describe the angle labels β_1–β_4.

The Applicants respectfully submit that the proposed drawing changes and the specification amendment do not introduce new matter. Approval of the proposed drawing changes and withdrawal of the pending drawing objection is respectfully requested.

2. <u>The Claims Are Patentable Under §§ 102(b) and 103(a)</u>.

The Applicants respectfully traverse the rejection of claims 1-5 as anticipated by, or in the alternative, as unpatentable over, Kubein-Meesenburg or Pappas, on the grounds that these reference fail to disclose or suggest all the features of the present invention.

The present invention is directed to an artificial knee joint wherein, *inter alia*, two offset contact surfaces are arranged such that at *every* flexion angle, the normals to the contact surfaces always meet at a common intersection point.[1] This feature is illustrated in the present figure, where the contact surfaces are

[1] For purposes of clarity, the Applicants have amended claim 1 to explicitly recite that the contact surfaces are contact points ("wherein the contact surfaces ... are <u>formed in each case by a point contact</u>," and that there is but a "<u>single</u>" common intersection point for every flexion angle.

shaped such that the normals to the surface contact points (*e.g.*, points C1), intersect at a single point (*e.g.*, point P1).

As a result of the surfaces being defined such that *every* pair of normals within a flexion range share the same intersection point (the contact surfaces being oriented "*as a function of* the knee joint flexion angle"), the joint becomes self-stabilizing when a rotational motion or torque about the tibia is introduced (*i.e.*, the geometry of the present invention's normals causes the effective lines of the forces introduced at the contact points to intersect). *See, e.g.*, Application ¶¶ [0010]-[0011]; Fig. 1. Even if the joint were to be laterally loaded (such that the tibia rotates relative to the femur), the joint remains self-stabilizing as the contact points are shifted with the rotation of the tibia (*e.g.*, to points C2). Application at [0018]-[0019]; Fig. 1. This is again due to the surfaces being shaped in accordance with the present invention's requirement that "surface normals of the contact surfaces have a single common point of intersection at each flexion angle," with the contact points now associated with a new intersection point (e.g., point P2) as the joint moves through its range of flexion angles. *Id.*

In contrast to the present invention, neither of the cited references disclose or suggest contact surface design which provides for normals at contact points on a contact surface to share a single common intersection point throughout a range of flexion angles.

Kubein-Meesenburg: The Kubein-Meesenburg reference teaches an approach to joint design where the curves of the opposing joint faces are

configured to ensure that the contact surface is always a contact *line*. *See, e.g.*, Kubein-Meesenburg at 1:35-45 ("The object ... is to create an artificial joint *in which point-like load transmission regions are avoided* ... this is achieved ... where on each of the articulation faces a curved *contact line* is formed ..." (emphasis added)).

Specifically, as shown in Kubein-Meesenburg Figs. 3-5, the contact surfaces are complex compound curves, defined by connecting a first contact point K (defined as the point at which a fixed cylinder (1) contacts a second cylinder (2) rotating about the first cylinder) with a second point Q rotating with rotating cylinder 2. Kubein-Meesenburg at 4:15-39 (surfaces defining the shape of the joint faces F1, F2 formed by straight lines B connecting point Q and point K as cylinder 2 rotates). In other words, the contact line surfaces of Kubein-Meesenburg are formed *without any reference to <u>any</u> normal line*, let alone normal lines from *separate* (*i.e.*, offset) surfaces, as recited in the present claims.[2]

Kubein-Meesenburg therefore neither discloses or suggests the present invention's artificial joint "wherein two contact surfaces ... are *offset* ... , and wherein the contact surfaces ... are formed in each case by a *point* contact and

[2] The fact that Kubein-Meesenburg's extended contact surface design is not based on management of normal geometry is further evidenced in this reference's inability to accommodate shock loads in the manner of the present invention. When a shock load is applied to the present invention, the tibia can rotate as necessary as the shock is absorbed, while still maintaining the desired surface contact at points which produce joint stability. Both Kubein-Meesenburg and Pappas have joints which cannot rotate without their joint faces lifting apart. Because such separation is not readily accommodated (body weight tending to preclude joint separation), shock loads can be directly transmitted at full intensity, rather than accommodated by relative motion, as in the present invention.

are arranged at an angle *as a function of the knee joint flexion angle* such that surface normals of the contact surfaces have a *single* common point of intersection at each flexion angle. Accordingly, reconsideration and withdrawal of the pending rejections based on Kubein-Meesenburg is respectfully requested.

Pappas: For its part, the Pappas reference also fails to disclose or suggest the design of a contact surface defined by a offset surface normals which share a single common intersection point.

Pappas also discloses continuous contour contact surfaces, rather than the point contact surfaces of the present invention. *See, e.g.,* Pappas 4:28-32 (femoral surface: "The geometry of the articulating surface 12 ... is a compound surface of revolution generated by revolving a generating curve 13 ... "); 4:37-50 (tibial surface: "... generated using .. a generating curve ... by simultaneously rotating and translating a surface of revolution"); 6:14-17 ("Thus, when the femoral and tibial components are disposed in the anatomical or neutral position, their engagement is one of a theoretical *line contact across the entire width of the femoral component* 10 (Fig. 4)."); *see also* Figs. 3, 4, 8.

As with Kubein-Meesenburg, there is neither a suggestion of any contact surface definition based on the common intersection of contact point normals throughout a flexion angle range, nor is there any disclosure in the drawings or the specification from which such congruence of normals can even be implied.

Because the Pappas reference also fails to disclose or suggest the present invention's intersecting normal-defined contact surface definition as recited in pending claim 1, this claim and its dependent claims 2-5 are patentable over this

reference under §§ 102(b) and 103(a). Accordingly, reconsideration and withdrawal of the pending §§ 102(b) and 103(a) rejections of the these claims is respectfully requested.

CONCLUSION

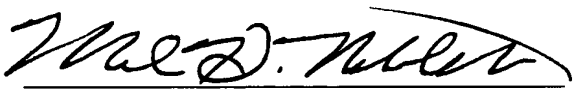
In view of the foregoing amendments and remarks, the Applicants respectfully submit that claims 1-5 are in condition for allowance. Early and favorable consideration and issuance of a Notice of Allowance for these claims is respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #038713.52491US).

Respectfully submitted,

November 16, 2004



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IN THE DRAWINGS:

Attached hereto for Examiner approval is a proposed replacement Fig. 1, showing changes to the figure in red ink.